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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS :	Soto et al.		
SERIAL NUMBER :	09/512,581	EXAMINER :	Stephen L. Rawlings, Ph.D
FILING DATE :	February 24, 2000	ART UNIT :	1642
FOR :	Novel Androgen-Induced Suppressor of Cell Proliferation and Uses Thereof		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PRIOR INVENTION UNDER 37 C.F.R. §1.132

We, Ana Soto, Peter Geck, Jozsef Szelei, and Carlos Sonnenschein, declare and state:

1. We are co-inventors of the subject matter described and claimed in United States patent application serial number 09/512,581, filed February 24, 2000, entitled "Novel Androgen-Induced Suppressor of Cell Proliferation and Uses Thereof".

2. We are co-authors of publication "Early gene expression during androgen-induced inhibition of proliferation of prostate cancer cells: a new suppressor candidate on chromosome 13, in the BRCA2-Rb1 locus", which was published in the Journal of Steroid Biochemistry and Molecular Biology 68:41-50, 1999.

3. Another co-author of this publication, Jesus Jimenez, worked under our direction and supervision and did not contribute to the conception of the claimed invention. Therefore, he is not a co-inventor of the subject matter claimed in the present patent application.

4. We have read, and are familiar with, the 09/512,581 patent application, and we understand that pending claims are directed to an isolated nucleic acid comprising the nucleotide sequences of SEQ ID NOs 1 and 3, which are the gene sequence and open reading frame encoding the Androgen Shutoff-3 (AS3) polypeptide, respectively.

5. We are aware that the United States Patent and Trademark Office has issued a final Office action. In particular, we understand that the Examiner has rejected the pending claims under 35 U.S.C. §§ 101 and 112, asserting that pending claims are not supported by a specific and substantial asserted utility or a well-established utility. This declaration is made in response to this assertion, with which we do not agree. The claimed compositions in my opinion have a specific and substantial utility for at least the following reasons.

6. We have performed, or have had performed under our supervision, studies evaluating differential expression of nucleic acid of SEQ ID NO: 3 in a prostate cell proliferative condition. Using anti-AS3 antibodies, we examined the abundance of the AS3 protein in normal humans and rats. AS3 was found to be abundantly expressed in the nuclei of prostate epithelial and stromal cells of normal tissue. we also examined the protein levels in prostate samples derived from over ten prostate cancer patients, and determined that AS3 was barely expressed in some prostate cancer tissue when compared to adjacent, non-cancerous prostate tissue from the same patient. In general, prostate cancer tissue showed variable expression of AS3 from none to intermediate levels, while normal tissue showed abundant expression. Thus, AS3 is useful in detection of prostate cancer tissue. Further, AS3 is expected to be useful to determine whether androgen treatment of prostate patients will be appropriate.

7. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.

Ana Soto — 5.10.04
Ana Soto — Date

Peter Geck — Date

Jozsef Szelei — Date

Carlos Sonnenschein — 5/10/04
Carlos Sonnenschein — Date

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